

REMARKS

Claims 1 and 3-67 are canceled herein. Claims 2, 68 and withdrawn claims 69, 74 and 80 are amended herein. Support for the amendment is found in the original claims. No new matter is presented.

Pending claims 69-76 and 80 are withdrawn from consideration. Applicants respectfully request rejoinder of pending composition and method of treatment claims which depend from or recite the elements of the allowable product claims of the elected invention.

I. Response to Objection to the Specification

According to the Examiner, page 5 of the specification at line 22 is vague because it states that “A” represents an acidic group, but no “A” is seen in formula (I) or earlier in the specification.

The Examiner also states that the Abstract of the disclosure is objected to because it exceeds 150 words in length.

The specification is amended herein by replacing “A” with “Z at page 5, line 21 and the Abstract is amended to reduce the number of words, thereby obviating the objections.

Accordingly, Applicants respectfully request withdrawal of the objections to the specification.

II. Claim Objections

Claim 1 is objected to because it recites that “A” represents an acidic group and there is no “A” in formula I.

Claim 1 is canceled herein, thereby rendering the objection moot.

III. Claim Rejections under 35 U.S.C. § 112, 1st Paragraph

Claims 1-2, and 68 are rejected under 35 U.S.C. § 112, first paragraph, allegedly because the specification does not reasonably provide enablement for numerous other A, B, D, and E rings and R¹, R², R³, R⁴, or R⁵ groups other than those for (4-{2-[3,5-dimethoxy-4-methylphenyl]-(hydroxyl)methyl]-5-phenylpentyl}phenyl)acetic acid.

Applicants respectfully traverse the rejection.

In making a determination of enablement, the proper inquiry is whether one of ordinary skill in the art would be able to use the claimed invention without undue experimentation. There are several factors which must be weighed and considered to determine whether any necessary experimentation can be considered as undue: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill in the art; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make and use the invention based upon the disclosure. See MPEP § 2164.01(a).

The PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. Applicants submit that the Examiner has not met his burden of providing a reasonable basis to question the enablement provided for the claimed invention. See also MPEP § 2164.01 and § 2164.04.

The Examiner asserts that there is only one example of compounds in the specification which is included within the scope of formula (I-B). However, Applicants respectfully disagree with the Examiner's assertion that the enablement requirement is not satisfied since considerable numbers of the compounds within the scope of formula (I-B) cannot be produced according to the examples and general production method described in the present specification.

First, Applicants are not limited by the synthesis examples in the specification. So even if there is only one representative compound of formula (I-B) in the specification, the claimed compounds would be enabled as long as one of ordinary skill in the art would be able to make and use other compounds within the scope of the claims based on the description that is provided in the specification and knowledge and skill available in the art.

Further, the Examiner's statement that only one compound within the scope of formula (I-B) is synthesized is not the proper test. A specification may be enabling without any working examples. See MPEP 2164.02. In this regard Applicants could point out other examples of the claimed compounds and argue that therefore, there is ample guidance for one skilled in the relevant art to make and/or use the claimed invention without undue experimentation.

Applicants' burden under 35 U.S.C. §112, first paragraph, is not to demonstrate that the instant compounds with all other possible substituents will retain the same properties, but to provide an enabling disclosure which teaches one skilled in the art to make and use the scope of the claimed invention without undue experimentation. Thus, even if the claims encompass inoperative species, the claims comply with the enablement requirement as long as undue experimentation is not necessary to determine which species would or would not work.

Applicants submit that it may be considered that, with only reference to the respective reactions described in the references cited by the Examiner, there is a case where a compound which is not desired (i.e., a compound which is outside the scope of the claims in some cases) is obtained as a main product. However, when it is expected that such a side reaction occurs, it is normal for the person skilled in the art to protect the other undesired reaction point or to modify the synthesis route adequately, based on the general knowledge. Even in the case where such an action is not taken, it cannot be considered that no objective compound can be obtained, although the yield might be low.

Notwithstanding the above, without conceding the merits of the rejection, the claims are amended to limit the compounds of the invention to compounds within the scope of formula (I-B) and the respective groups in formula (I-B) are amended.

Furthermore, in response to the Examiner's assertion that pharmacological activity data with regard to the claimed compounds is not sufficiently shown, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 showing data regarding pharmacological activity data regarding compounds within the scope of the present amended claims.

In view of the above, Applicants respectfully request withdrawal of the rejection.

IV. Response to Claim Rejection under 35 U.S.C. § 112, 2nd Paragraph

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner asserts that claim 1 recites the limitation that "A" represents an acidic group and there is no "A" group present in formula I.

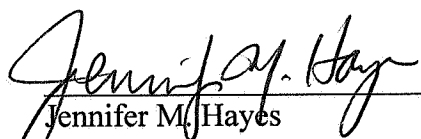
Claim 1 is canceled herein, thereby rendering the rejection moot. Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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